



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

WARNING LETTER

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 3, 2006

W/L 35-06

Mr. Ginichi Y. Ohira, President
E-Fish Network Corporation
1472 W. 178th Street
Gardena, CA 90248-3202

Dear Mr. Ohira:

We inspected your seafood importer establishment, located at 1472 W. 178th Street, Gardena, CA 90248-3202 on April 6 & 19, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123.

In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR Part 123. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 342(a)(4)), and will be denied entry. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

21 C.F.R. § 123.12 requires that you either obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the FDA that covers the fish or fishery products you import, or have and implement written verification procedures to verify that your foreign suppliers have implemented Hazard Analysis Critical Control Point (HACCP) in accordance with FDA's requirements. These verification procedures must include product specifications to preclude safety hazards and, at a minimum, one or more affirmative steps (21 CFR 123.12(a)(2)). Affirmative steps may include the following:

- (A) Obtaining from the foreign processor the HACCP and sanitation monitoring records

required by this part that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or;

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

The firm from which you obtain your mackerel, amberjack and shellfish, [REDACTED], is not listed as a certified seafood processor by [REDACTED] (For a full listing of certified seafood processors in [REDACTED], please see: <http://www.cfsan.fda.gov/~frf/sfimport.html> .) Therefore, your firm must have and implement written verification procedures to verify that your [REDACTED] suppliers have implemented the FDA-required Hazard Analysis Critical Control Point (HACCP) in order to be in compliance.

Because our inspection identified serious violations for 21 CFR Part 123, your mackerel, amberjack and fresh shellfish appear to be adulterated under Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Your significant violations were as follows:

- You must implement an affirmative step which ensures that the fish and fishery product you import are processed in accordance with the seafood HACCP regulation, to comply with 21CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for mackerel, amberjack and fresh shellfish manufactured by [REDACTED] in [REDACTED]
- You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health to comply with 21CFR 123.12(a)(2)(i). However, your firm does not have a product specification for mackerel, amberjack and fresh shellfish imported from [REDACTED]

We may take further action if you do not promptly correct these violations. For instance, we may refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. § 381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

In addition to the concerns addressed above, during the inspection on April 6 & 19, 2006, the examination of entry [REDACTED] was also discussed. An FDA examination was conducted of entry [REDACTED] upon entry into the United States. This entry was found to have undeclared raw shellfish and Tiger Puffer fish, *Takifugu rubripes* (also known as fugu fish) concealed within the shipment. Please be aware that puffer fish are subject to strict importing requirements under Import Alert 16-20. In a statement to our investigators you explained that the fugu fish was not knowingly imported by your firm and that it was destined to local stores in [REDACTED]; however, after having the paper tags on the fugu fish translated, it identified the type of fish and the customer in [REDACTED] to whom it was intended. Of the four packages of fugu fish, one was identified with the name of one of your retail customers, a sushi restaurant.

Making fraudulent misrepresentations or false statements to federal officials is a criminal offense under Title 18, United States Code, Section 1001 (18 U.S.C § 1001). Likewise, entering or attempting to enter imported goods into the United States by means of a false statement, including the omission of material facts about the imported goods, is also a criminal offense (18 U.S.C. § 542), as is entry of goods contrary to law (18 USC 545) may result in addition to the charges mentioned above. Criminal offenses can result in imprisonment, fines, or both.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation, such as HACCP and importer verification records and records that document the performance and results of your firm's affirmative steps, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

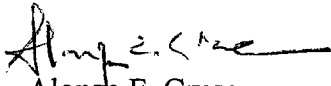
Please send your reply to:

Food and Drug Administration,
Attention: J. Lawrence Stevens,
Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

Mr. Ginichi Y. Ohira, E-Fish Network Corporation
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If you have questions regarding any issues in this letter, please contact Ruth P. Dixon,
Compliance Officer at (310)971-2299.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse", with a horizontal line extending to the right.

Alonza E. Cruse
District Director
Los Angeles District

Cc: Department of Health Services
Food and Drug Branch
P.O. Box 997413, MS-7602
Sacramento, CA 95899-7413